

PATENT COOPERATION TREATY

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REC'D 28 MAR 2006


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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 4530PTW/AG/la		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/EP2004/053251		International filing date (day/month/year) 03.12.2004		Priority date (day/month/year) 03.12.2003
International Patent Classification (IPC) or national classification and IPC A61B5/113, A61B5/0408				
Applicant MILIOR S.P.A. et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 29.09.2005		Date of completion of this report 28.03.2006		
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Knüpling, M Telephone No. +31 70 340-2891		



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/053251

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-7 as originally filed

Claims, Numbers

1-21 received on 03.10.2005 with letter of 03.10.2005

Drawings, Sheets

1/4-4/4 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/053251

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-21
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: PARADISE R ET AL: "Knitted bioclothes for cardiopulmonary monitoring"
D2: GB-A-1 417 394
D3: WIJESIRIWARDANA R ET AL: "Resistive fibre-meshed transducers"

1. Independent claims 1, 16 - 19

1.1

The present application does not meet the requirements of Article 33(3) PCT, because the subject-matter of claims 1, 13 - 19 does not involve an inventive step. The reasons are the following:

Document D1 discloses (the references in parenthesis applying to this document):

Knitted fabric wherein piezoresistive sensors for the monitoring of movement and breathing, electrodes for the monitoring of cardiac activity and breathing, and conductive connections for the transmission of signals are integrated (abstract; figure 2).

1.2

Consequently, the subject-matter of claim 1 differs from D1 in the feature that

said knitted fabric is made of multiple layers where sensors, electrodes and connections are located.

1.3

D3 relates to wearable patient monitoring systems using knitted structures comprising strain gauges (D3, p. 2, section 2 'Significance of knitting technology'). Thus, D3 relates to

the same general subject as the application (p. 3, l. 7 - 12) and D1 (abstract). Furthermore, D3 discloses that advantageously such a knitted structure is composed of multiple layers (D3, p. 2, section 2 'Significance of knitting technology', last paragraph).

Consequently, the skilled person would regard it as obvious to include this feature known from D3 in a device according to D1 in order to solve the problem posed.

The subject-matter of claim 1 can therefore not be considered as involving an inventive step (Article 33(3) PCT).

Since D1 also refers to detecting breathing pattern (section II, second sentence) and breathing signals are related to movement, claim 17 also lacks an inventive step (Article 33(3) PCT).

1.4

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 16, 18, and 19 does not involve an inventive step in the sense of Article 33(3) PCT.

1.5

With regard to claim 16, D1 refers to monitoring activity, ECG, and breathing pattern (section II, first para.). For the man skilled in the art, breathing patterns obviously include breathing activity and respiratory frequency. Thus, claim 16 discloses in addition to what is known from D1 detection of EOG and EMG signals. However, the man skilled in the art known about these signals and according to circumstances, would use the known fabric according to D1 and D3 for the detection of EOG and EMG signals without applying an inventive step.

1.6

With regard to claim 18, the same arguments, *mutatis mutandis*, as for claim 16 apply. Impedance pneumography is well known in the art and would obviously applied by the man skilled in the art.

1.7

With regard to claim 19, a double-bed jersey technique is a well known technique in the

field of knitting (see also D2, Example 13) and cannot support an inventive step.

1.8

Thus, claims 16, 18, and 19 lack an inventive step (Article 33(3) PCT).

2. Dependent claims

2.1

Claims 12, 13, and 15 do not comply with the requirements of Rule 6.2 PCT since they refer to the drawings.

2.2

The features of claim 14 are obvious in view of D1 (section 'Conclusion') since 'cut and sew' is a standard textile industrial process.

2.3

Dependent claims 2 - 11, 20, 21 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to inventive step, since they are either disclosed by D1 or D3, or rendered obvious by the prior art (see passages cited in the search report).

NEW SET OF CLAIMS

1. Knitted fabric wherein piezoresistive sensors for the monitoring of movement and breathing, electrodes for the monitoring of cardiac activity and breathing, and
5 conductive connections for the transmission of signals are integrated, characterised in that said knitted fabric is made of multiple layers where sensors, electrodes and connections are located.
2. Knitted fabric according to claim 1 wherein said piezoresistive sensors are realised by
10 regions of fabric made of piezoresistive yarns.
3. Knitted fabric according to claim 1-2 wherein said piezoresistive sensors are realised by the so-called "intarsia" technique.
- 15 4. Knitted fabric according to claim 1-3 wherein said electrodes and said conductive connections are realised by conductive yarns.
5. Knitted fabric according to claim 1-4 wherein said electrodes and said conductive connections are made using the so-called "tubular intarsia technique".
20
6. Knitted fabric according to claim 1-5 wherein said electrodes are made of metal yarns twisted with standard yarns.
7. Knitted fabric according to claim 1-6 wherein said piezoresistive yarns are elastic
25 yarns composed by electro-conductive fibres or synthetic fibres containing dispersed phases or shells of conductive materials.
8. Knitted fabric according to claim 1-7 wherein said piezoresistive yarns are made with a lycra-based fabric coated with carbon loaded rubber.
30
9. Knitted fabric according to claim 1-8 wherein said conductive connections are made of metal yarns twisted with standard yarns.
10. Knitted fabric according to claim 1-9 wherein said knitted fabric is made using the
35 double-bed jersey technique.

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11. Knitted fabric according to claim 1-10 wherein said knitted fabric is made of multiple layers in a way that electrodes are placed in contact with the skin of the user under examination while connections are insulated by a layer of fabric which separates them from the user's body.
- 5
12. Knitted fabric according to claim 1-11 wherein said piezoresistive sensors and said electrodes are located as reported on figure (1).
- 10
13. Knitted fabric according to claim 1-11 wherein said electrodes are located as reported on figure (6).
14. Knitted fabric according to claim 1-12 wherein said knitted fabric is employed in cut and sewn clothes and garments.
- 15
15. Knitted fabric according to claim 13 wherein the sleeves comprised in said clothes and garments have a shape that is cut from said fabric, rotated with respect to knitting direction so that course in said sleeves are parallel to arm length.
- 20
16. Use of the knitted fabric according to claim 1 - 15 for the detection of signals related to ECG, EOG, EMG, respiratory activity and respiratory frequency.
17. Use of the knitted fabric according to claim 1 - 15 for the detection of signals related to movement activity.
- 25
18. Use of the knitted fabric according to claim 1 - 15 for the detection of impedance pneumography.
19. Process for the production of a knitted fabric according to claim 1-15 wherein said knitted fabric is made using the double-bed jersey technique.
- 30
20. Process according to claim 19 wherein said electrodes and said conductive connections are made using the so-called "tubular-intarsia technique".
- 35
21. Process according to claim 20 wherein said knitted fabric is made with double bed weft knitting machines.

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Box No. VIII (iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America)
The declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.

**Declaration of inventorship (Rules 4.17(iv) and 51bis.1(a)(iv))
 for the purposes of the designation of the United States of America:**

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This declaration is directed to international application No. PCT/EP/2004/053251, (if furnishing declaration pursuant to Rule 26ter).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

Prior Applications: .. Italy - Application No. FI2003A000308 filed on 3 December 2003

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.


I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Date: 22 March 2005
 (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Name: ..

Residence: ..
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Citizenship: ..

Inventor's Signature: ..
 (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: ..
 (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII (iv)".